EFFECTS OF SWITCHING TO VERY LOW NICOTINE CIGARETTES ON SMOKING BEHAVIOR

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INTRODUCTION

- A number of studies have shown reductions in smoking and increases in quitting after switching to cigarettes made from tobacco with a very low nicotine content (VLN cigarettes).[1, 2, 3, 4]
- This poster presents data on smoking of study and non-study cigarettes by 234 participants in a trial of VLN cigarettes as a smoking cessation aid.
- The VLN cigarettes used in this study had a nicotine content of about one-half to one-third that of VLN cigarettes used in published studies (approximately 0.5 mg/g, vs. 1 to 1.5 mg/g).

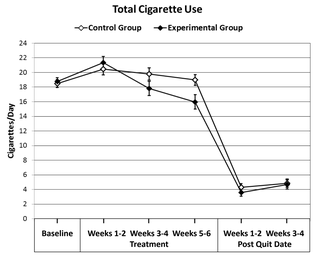


Figure 1. Total average daily cigarette use (sum of reported study and non-study cigarette use) during baseline (1 week) treatment (3 x 2 weeks) and post quit date (2 x 2 weeks). Bars indicate SE.

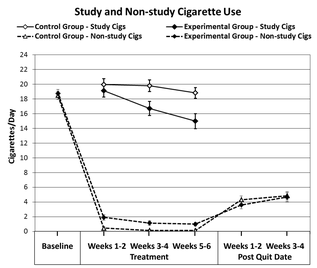


Figure 2. Study and Non-study cigarette use reported during baseline (1 week) treatment (3 x 2 weeks) and post quit date (2 x 2 weeks). Bars indicate SE.

Table 2. Non-Study Cigarette Use During Treatment Period

	Treatment Weeks 1-2				Treatment Weeks 3-4				Treatment Weeks 5-6			
	n (%)	Total Cigs/Day mean (SD)	NS Cigs/Day mean (SD)	NS Cigs/ Total Cigs	n (%)	Total Cigs/Day mean (SD)	NS Cigs/Day mean (SD)	NS Cigs/ Total Cigs	n (%)	Total Cigs/Day mean (SD)	NS Cigs/Day mean (SD)	NS Cigs/ Total Cigs
Experimental Group	106	21.3 (8.7)	1.9 (3.9)	8.9%	95	17.8 (9.4)	1.1 (3.0)	6.2%	88	16.0 (9.3)	1.0 (2.5)	6.2%
Smoking Study and Non-Study Cigarettes	65 (61%)	21.0 (7.8)	3.1 (4.6)	14.8%	43 (45%)	17.1 (8.1)	2.5 (4.1)	14.6%	35 (40%)	16.5 (7.9)	2.5 (3.5)	15.2%
Smoking Study Cigarettes only	41 (39%)	21.9 (10.0)	-	-	52 (55%)	18.4 (10.6)	-	-	53 (60%)	15.7 (10.3)	-	-
Control Group	110	20.4 (8.3)	0.5 (1.4)	2.5%	106	19.8 (8.5)	0.1 (0.8)	0.5%	100	19.0 (7.3)	0.1 (0.7)	0.5%
Smoking Study and Non-Study Cigarettes	41 (37%)	21.7 (10.0)	1.3 (2.0)	6.0%	15 (14%)	19.9 (5.9)	1.0 (1.9)	5.0%	12 (12%)	16.0 (8.8)	1.2 (1.6)	7.5%
Smoking Study Cigarettes only	69 (63%)	19.7 (7.1)	-	-	91 (86%)	19.8 (6.7)	-	-	88 (88%)	19.5 (6.9)	-	-

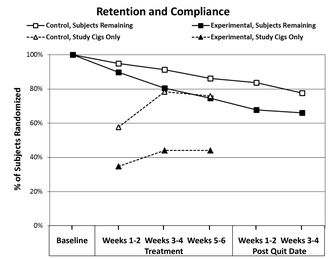


Figure 6. Retention of subjects and subjects using only Study Cigarettes during the treatment period by group as a proportion of the intent to treat population.

METHODS

Study Design

- The smoking data presented here was taken from a double-blind, randomized, active controlled, parallel group, study of VLN cigarettes as a potential smoking cessation aid (registered as NCT01400815 at clinicaltrials.gov).
- Following a one week baseline observation, participants were provided biweekly with VLN cigarettes (Experimental Group) or active control cigarettes (Control Group) for 6 weeks prior to a scheduled quit date.
- Participants also received approximately 15-minute individual counseling sessions including distribution of printed materials 2 weeks prior to the quit date, at the quit date, and 2 weeks after the quit date.

Participants

- 234 healthy smokers of at least 10 cigarettes per day for at least 1 year, with and exhaled CO measurement of ≥ 10 ppm at baseline, who had expressed a desire to quit smoking within 3 months.
- Participants were recruited at 3 locations in the U.S.
- Baseline characteristics for the smokers in each of the groups are provided in Table 1.

Materials

- Experimental VLN cigarette: Made with very low nicotine tobacco cigarette filler having 0.5 mg/gdw nicotine content; ISO yields (mg/cigarette): "Tar," 6.9; Nicotine, 0.03; CO, 13.1 mg/cigarette.
- Active Control Cigarette: Identical to the VLN cigarette except that it was made with conventional tobacco cigarette filler with 23.8 mg/gdw nicotine; ISO yields: "Tar," 8.7; Nicotine, 0.71; CO, 11.8.
- All study cigarettes contained menthol, which was incorporated in the filters used in manufacturing the cigarettes.

Measures

- Study and Non-study cigarettes smoked (diary).
- Corrected Exhaled CO (at biweekly visits).

Table 1. Participant Characteristics

	Experimental Group	Control Group
Randomized Subjects (n)	118	116
Gender, female (n, %)	54 (45.8%)	52 (44.8%)
Race, White (n, %)	88 (74.6%)	81 (69.8%)
Age, mean (SD)	42.1 (11.0)	41.8 (11.2)
Age at Onset of Smoking (mean, SD)	16.9 (5.3)	17.5 (6.4)
Prior quit attempts (mean, SD)	3.3 (4.6)	3.8 (7.9)
Cigarettes/day (mean, SD)	20.5 (6.6)	20.5 (5.5)
Menthol use (n, %)	53 (44.9%)	48 (41.4%)
Exhaled CO at screening, ppm (mean, SD)	22.2 (9.5)	23.3 (8.9)

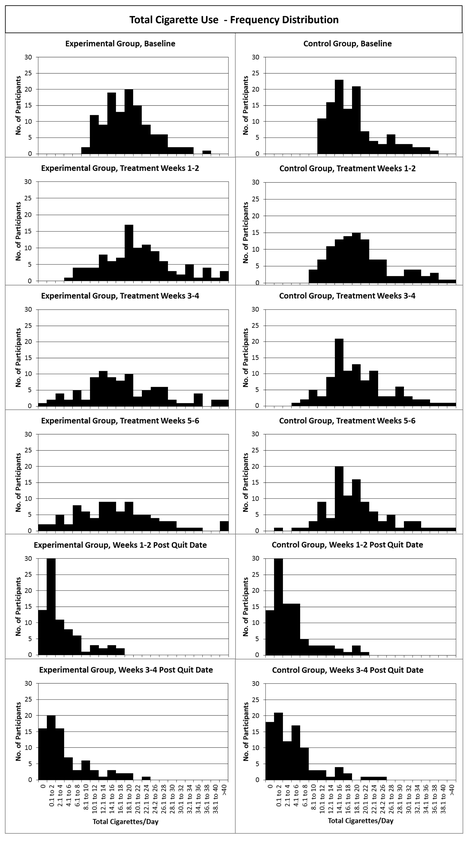


Figure 3. Frequency distribution of average Total Cigarettes/Day reported by each participant (all subjects with data) during baseline (1 week) treatment (3 x 2 weeks) and post quit date (2 x 2 weeks). Left panels, Experimental Group, right panels Control Group.

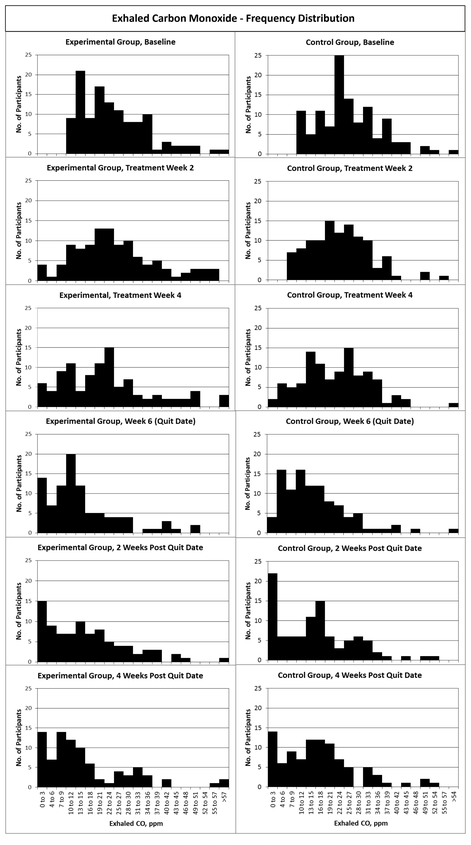


Figure 4. Frequency distribution of Exhaled CO values recorded at each visit (all subjects with data) after 1 week baseline, after 2 and 4 weeks of treatment, at the quit date, and 2 and 4 weeks post quit date. Left panels, Experimental Group, right panels Control Group.

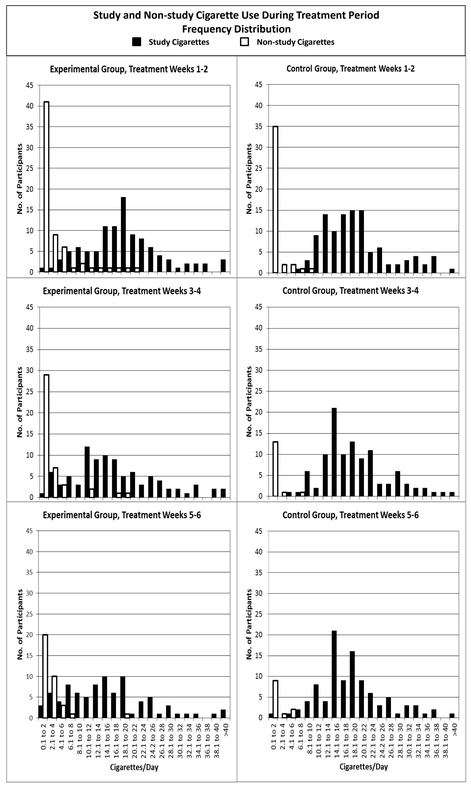


Figure 5. Frequency distribution of non-zero average Study Cigarettes/Day and Non-Study Cigarettes/Day reported by participants during baseline (1 week) treatment (3 x 2 weeks) and post quit date (2 x 2 weeks). Left panels, Experimental Group, right panels Control Group. Numbers of subjects reporting zero values are omitted to avoid compression of the scale due to the numbers of participants reporting zero non-study cigarettes; these values are provided in Table 2.

RESULTS

- Average daily total cigarette use initially increased in both groups, and then declined in the VLN cigarette group over the 6 week treatment period. After the quit date average cigarette use was less than 25% of baseline, but did not differ significantly between groups. (Figure 1)
- The low average reported cigarette use after the quit date reflects reported use of a small, but non-zero, number of cigarettes/day by a large proportion of the study population. (Figure 3)
- Although exhaled CO reflects smoking over only the recent past, the frequency distributions of CO readings show the same patterns as the cigarette diary data. (Figure 4)
- Although the average use of non-study cigarettes during the treatment period was low, it was significantly higher in the VLN cigarette group. (Figure 2)
- The greater average use of non-study cigarettes during the treatment period by participants in the VLN cigarette group reflects both use of non-study cigarettes by a larger proportion of the VLN group, and smoking of a larger number of NS cigarettes by those that do smoke them. (Table 2 and Figure 5)
- The retention of subjects in the VLN cigarette group was lower than in the active control cigarette group. Although 60% of the participants remaining in the VLN cigarette group at the end of treatment reported no non-study cigarette use during the last 2 weeks of treatment, this represents 45% of the intent to treat population. (Figure 6)

DISCUSSION

Previously available cigarettes with very low nicotine content (Quest 3®, Xodus®) contained 1 to 1.5 mg nicotine per g of filler, a reduction of up to 95% compared to the content of typical cigarettes. The VLN cigarettes used in the study from which the data presented here was taken had a nicotine content of about 0.5 mg/g, a reduction of ca. 97%. While this is a small absolute difference, it appears that compliance with the use of the VLN cigarettes may have been lower. While few participants reported returning to smoking large numbers of their usual brand, many reported concomitant use of a few regular cigarettes per day. If extinction of the association of smoking with nicotine reward is a mechanism by which VLN cigarettes can reduce smoking, intermittent use of regular cigarettes may undermine the effect.

REFERENCES

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